DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10912]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by May 1, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA); *Use:* Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (*Pub. L. 117–169*), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (''the Act''). The Act establishes the Negotiation Program to negotiate maximum fair prices (''MFPs''), defined at 1191(c)(3) of the Act, for certain high expenditure, single source selected drugs covered under Medicare Part B and Part D (''selected drugs''). In accordance with section 1193(a) of the Act, any Primary Manufacturer of a selected drug that continues to participate in the Negotiation Program and reaches agreement upon an MFP must provide access to the MFP to MFP-eligible individuals, defined in section 1191(c)(2)(A) of the Act, and to pharmacies, mail order services, other dispensing entities, providers and suppliers with respect to such MFP-eligible individuals who are dispensed that selected drug during a price applicability period. The purpose of this information collection request (ICR) is for CMS to collect information from manufacturers of drugs covered under Part D selected for negotiation under the Inflation Reduction Act for the initial price applicability years 2026 and 2027 and the dispensing entities that dispense the selected drugs to MFP-eligible individuals. To facilitate the effectuation of the MFP, CMS will engage a Medicare Transaction Facilitator (''MTF''). The MTF system will be composed of two modules: the MTF Data Module (MTF DM), and the MTF Payment Module (MTF PM).

Medicare Transaction Facilitator Data Elements: The MTF system will be composed of two modules: the MTF Data Module (MTF DM), and the MTF Payment Module (MTF PM). Primary Manufacturers participating in the Negotiation Program are required to participate in the MTF DM. Further, CMS intends to propose in future rulemaking to require Part D plan sponsors to include in their pharmacy agreements provisions requiring dispensing entities to participate in the MTF DM for purposes of data exchange. As such, for the purposes of this ICR, CMS assumes full participation in the MTF DM by affected Primary Manufacturers and dispensing entities. Meanwhile, participation in the MTF PM, for use in passing through payment from the Primary Manufacturer to dispensing entities, will be optional for Primary Manufacturers; as a result, dispensing entities may receive fund transfers from the MTF PM, or via an alternative process established by a Primary Manufacturer. As discussed in section 40.4 of the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (''final guidance''),[1] CMS will engage the MTF DM to facilitate the exchange of certain claim-level data elements and payment elements for selected drugs. The data exchange component of the MTF will involve both the transmission of certain claim-level data elements to the Primary Manufacturer and receipt of claim-level payment elements from the Primary Manufacturer. Both Primary Manufacturers and dispensing entities will need to provide certain information at the onset of their enrollment in the MTF DM system to facilitate effectuation of the MFP via refunds from Primary Manufacturers. Both Primary Manufacturers and dispensing entities will be able to submit complaints and disputes through their participation in the MTF DM. Primary Manufacturers

[1] *https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.*

will also submit information to fulfill their requirement to provide an MFP Effectuation Plan and transmit recurring data submissions reflecting their payment elements, as described in the final guidance. Given these information collection requirements, this ICR includes the following forms: (A) Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Enrollment Form; (B) Drug Price Negotiation Program MTF DM Primary Manufacturer Maximum Fair Price (MFP) Effectuation Plan Form; (C) Drug Price Negotiation Program MTF DM Primary Manufacturer Payment Elements Form; and (D) Drug Price Negotiation Program Complaint and Dispute Intake Form. *Form Number:* CMS–10912 (OMB control number: 0938–New); *Frequency:* Once and Daily; *Affected Public:* Private sector, Business or other for-profit, and individuals; *Number of Respondents:* 85,853; *Total Annual Responses:* 93,120; *Total Annual Hours:* 877,510. (For policy questions regarding this collection contact Brennan Folsom at 667–414–0014.)

Trenesha Fultz-Mimms,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2025–05530 Filed 3–27–25; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Effect of HIV and Substance Use Comorbidity on the Placenta and Maternal Outcomes.

Date: April 28, 2025.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Devon Rene Oskvig, Ph.D., Scientific Review Officer, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 402–6965, *devon.oskvig@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: March 27, 2025.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–05562 Filed 3–31–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Inherited Disease Research Access Committee.

Date: May 9, 2025.

Time: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Room 3172, Bethesda, MD 20892.

Meeting Format: Virtual.

Contact Person: Barbara J. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Room 3172, Bethesda MD 20817, 301–402–8837, *barbara.thomas@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: March 26, 2025.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–05515 Filed 3–31–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Child Health and Human Development Council.

Date: June 9–10, 2025.

Open: June 09, 2025, 12:00 p.m. to 3:45 p.m.

Agenda: Call to order and introductory remarks; Director's Report; Voice of the Participant; Council Business.

Meeting Format: Virtual Meeting.

Address: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892.

Closed: June 10, 2025, 9:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Meeting Format: Virtual Meeting.

Address: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rebekah S. Rasooly, Ph.D., Director, Division of Extramural Activities, *Eunice Kennedy Shriver* National Institute of